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PATENT

Case Docket No. NIH218.001C1

Date: July 12, 2004

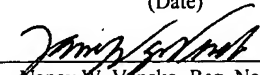
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Gu, Xin-Xing  
Appl. No. : 10/688,115  
Filed : October 17, 2003  
For : INTRANASAL  
IMMUNIZATION WITH  
DETOXIFIED  
LIPOOLIGOSACCHARIDE  
FROM NONTYPEABLE  
HAEMOPHILUS  
INFLUENZAE OR  
MORAXELLA  
CATARRHALIS  
Examiner : Unknown  
Group Art Unit : 1653

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

July 12, 2004

(Date)

  
Nancy W. Vensko, Reg. No. 36,298

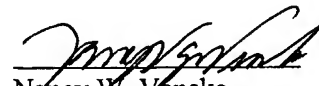
TRANSMITTAL LETTER

Mail Stop: Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are:

- (X) An Information Disclosure Statement.
- (X) A PTO Form 1449 with fifty-three (53) references.
- (X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.

  
Nancy W. Vensko  
Registration No. 36,298  
Attorney of Record  
Customer No. 20,995  
(805) 547-5580



## INFORMATION DISCLOSURE STATEMENT

Applicant : Gu, Xin-Xing  
App. No. : 10/688,115  
Filed : October 17, 2003  
For : INTRANASAL IMMUNIZATION WITH  
DETOXIFIED LIPOOLIGOSACCHARIDE FROM  
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OR MORAXELLA CATARRHALIS  
Examiner : Unknown  
Group Art Unit : 1653

Mail Stop: Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:


Enclosed is form PTO-1449 listing 53 references. Copies of disclosed U.S. patents and/or publications are not included pursuant to PTO waiver of the requirement under 37 C.F.R. § 1.98(a)(2)(i) for applications filed after June 30, 2003. Copies of other references, if listed, are enclosed.

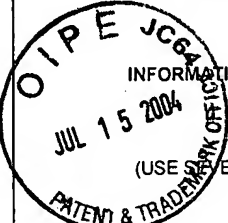
This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required in accordance with 37 C.F.R. § 1.97(b)(3).

If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,  
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 7/12/04

By:   
Nancy W. Vensko  
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Attorney of Record  
Customer No. 20,995  
(805) 547-5580

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (USE SEVERAL SHEETS IF NECESSARY)	ATTY. DOCKET NO. NIH218.001C1	APPLICATION NO. 10/688,115
	APPLICANT Gu, Xin-Xing	
	FILING DATE October 17, 2003	GROUP 1653

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	1.	US 5,601,831	02/11/1997	Green et al.			
	2.	US 5,607,846	03/04/1997	Murphy et al.			
	3.	US 5,770,213	06/23/1998	Zlotnick			
	4.	US 5,948,412	09/07/1999	Murphy			
	5.	US 5,955,580	09/21/1999	Green et al.			
	6.	US 6,207,157	03/27/2001	Gu et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	7.	WO 99/36086	07/22/1999	PCT				

EXAMINER  
INITIAL

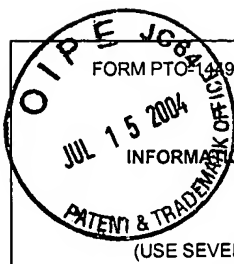
## OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

	8.	Asanuma, H. et al. "Isolation and characterization of mouse nasal-associated lymphoid tissue." <i>J. Immunol. Methods</i> <b>202</b> (1997), pp. 123-131.
	9.	Barenkamp S.J. et al. "Development of serum bactericidal activity following nontypable <i>Haemophilus influenzae</i> acute otitis media." <i>Pediatr. Infect. Dis. J.</i> <b>9</b> (1990), pp. 333-339.
	10.	Bergquist, C. et al. "Antibody responses in serum and lung to intranasal immunization with <i>Haemophilus influenzae</i> type b polysaccharide conjugated to cholera toxin B subunit and tetanus toxoid." <i>Apmis</i> <b>106</b> (1998), pp. 800-806.
	11.	Berman, S. "Otitis media in children." <i>New Engl. J. Med.</i> <b>332</b> (1995), pp. 1560-1565.
	12.	Bernstein, J.M. et al. "Micro-ecology of the nasopharyngeal bacterial flora in otitis-prone and non-otitis-prone children." <i>Acta Otolaryngol.</i> <b>113</b> (1993), pp. 88-92.
	13.	Brook, I. et al. "Microbiologic characteristics of persistent otitis media." <i>Arch. Otolaryngol. Head Neck Surg.</i> <b>124</b> (1998), pp. 1350-1352.
	14.	Campagnari, A.A. et al. "Antigenic diversity of lipooligosaccharides of nontypable <i>Haemophilus influenzae</i> ." <i>Infect. Immun.</i> <b>55</b> (1987), pp. 882-887.
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	16.	Cripps, A.W. et al. "Respiratory immunity stimulated by intestinal immunization with purified nontypeable <i>Haemophilus influenzae</i> antigens." <i>J. Infect. Dis.</i> <b>165</b> (1992), pp. S199-S201.
	17.	DeMaria, T.F. et al. "Evaluation of the virulence of nontypeable <i>Haemophilus influenzae</i> lipooligosaccharide htrB and rfaD mutants in the chinchilla model of otitis media." <i>Infect. Immun.</i> <b>65</b> (1997), pp. 4431-4435.
	18.	Faden, H. et al. "Relationship between nasopharyngeal colonization and the development of otitis media in children." <i>J. Infect. Dis.</i> <b>175</b> (1997), pp. 1440-1445.
	19.	Gu, X.X. et al. "Production and characterization of monoclonal antibodies to type 8 lipooligosaccharide of <i>Neisseria meningitidis</i> ." <i>J. Clin. Microbiol.</i> <b>30</b> (1992), pp. 2047-2053.

EXAMINER

DATE CONSIDERED

\*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. NIH218.001C1	APPLICATION NO. 10/688,115
	APPLICANT Gu, Xin-Xing			
	FILING DATE October 17, 2003		GROUP 1653	

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)	
	20.	Gu, X.X. et al. "Quantitation and biological properties of released and cell-bound lipooligosaccharides from nontypeable <i>Haemophilus influenzae</i> ." <i>Infect. Immun.</i> <b>63</b> (1995), pp. 4115-4120.
	21.	Gu, X.X. et al. "Synthesis, characterization, and immunologic properties of detoxified lipooligosaccharide from nontypeable <i>Haemophilus influenzae</i> conjugated to proteins." <i>Infect. Immun.</i> <b>64</b> (1996), pp. 4047-4053.
	22.	Gu, X.X. et al. "Detoxified lipooligosaccharide from nontypeable <i>Haemophilus influenzae</i> conjugated to proteins confers protection against otitis media in chinchillas." <i>Infect. Immun.</i> <b>65</b> (1997), pp. 4488-4493.
	23.	Gu, X.X. et al. "Development of a vaccine to prevent Otitis media caused by <i>Nontypeable Haemophilus Influenzae</i> " The 4 <sup>th</sup> Extraordinary International Symposium on Recent Advances in Otitis Media, Sendai, Japan, April 16-20, (2001), Abstract 72, p. 116.
	24.	Hirano, T. et al. "Intranasal immunization with a lipooligosaccharide-based conjugate vaccine from nontypeable <i>Haemophilus influenzae</i> enhances bacterial clearance in mouse nasopharynx." <i>FEMS Immunol. Med. Microbiol.</i> <b>35</b> , (2003), pp. 1-10.
	25.	Hotomi, M. et al. "Specific mucosal immunity and enhanced nasopharyngeal clearance of nontypeable <i>Haemophilus influenzae</i> after intranasal immunization with outer membrane protein P6 and cholera toxin." <i>Vaccine</i> <b>16</b> (1998), pp. 1950-1956.
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	27.	Kauppi-Korkeila, M. et al. "Mechanism of antibody-mediated reduction of nasopharyngeal colonization by <i>Haemophilus influenzae</i> type b studied in an infant rat model." <i>J. Infect. Dis.</i> <b>174</b> (1996), pp. 1337-1340.
	28.	Kodama, S. et al. "Induction of specific immunoglobulin A and Th2 immune responses to P6 outer membrane protein of nontypeable <i>Haemophilus influenzae</i> in middle ear mucosa by intranasal immunization." <i>Infect. Immun.</i> <b>68</b> (2000), pp. 2294-2300.
	29.	Kurono, Y. et al. "Effects of oral and systemic immunization on nasopharyngeal clearance of nontypeable <i>Haemophilus influenzae</i> in BALB/c mice." <i>Laryngoscope</i> <b>106</b> (1996), pp. 614-618.
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	40.	Phillips, N.J. et al. "Structural characterization of the cell surface lipooligosaccharides from a nontypable strain of <i>Haemophilus influenzae</i> ." <i>Biochemistry</i> 31 (1992), pp. 4515-4526.
	41.	Rahman, M.M. et al. "The structural heterogeneity of the lipooligosaccharide (LOS) expressed by pathogenic nontypeable <i>Haemophilus influenzae</i> strain NTHi 9274." <i>Glycobiology</i> 9 (1999), pp. 1371-1380.
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	44.	Shen, X. et al. "Systemic and mucosal immune responses in mice after mucosal immunization with group B streptococcus type III capsular polysaccharide-cholera toxin B subunit conjugate vaccine." <i>Infect. Immun.</i> 68 (2000), pp. 5749-5755.
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	53.	Wu T.H. et al. "Outer membrane proteins as a carrier for detoxified lipooligosaccharide conjugate vaccines for nontypeable <i>Haemophilus influenzae</i> ." <i>Infect. Immun.</i> 67 (1999), pp. 5508-5513.

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